4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-NEW and title "De Novo Classification Process (Evaluation of Automatic Class III Designation)." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

De Novo Classification Process (Evaluation of Automatic Class III Designation)

OMB Control Number 0910-NEW

The draft guidance entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)" provides guidance on the process for the submission and review of a De Novo classification request (hereafter a "De Novo request") under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)), also known as the De Novo classification process. This process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

The proposed collection of information is necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

In the *Federal Register* of August 14, 2014 (79 FR 47651), FDA published a 60-day notice requesting public comment on the proposed collection of information. Seven organizations commented on the draft guidance document. None of the comments were related to the information collection.

Upon further review of the information collection, it has come to our attention that the 60-day notice did not include an estimated hour burden for requests for withdrawal or estimated

operating and maintenance costs for eCopy,[1] printing, and shipping of De Novo submissions. To correct this oversight, we have included these estimates here.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
De Novo request under section 513(f)(2)(i) of the FD&C Act						
CDRH	25	1	25	100	2,500	
CBER	1	1	1	100	100	
De Novo request under section 513(f)(2)(ii) of the FD&C Act						
CDRH	25	1	25	180	4,500	
CBER	1	1	1	180	180	
Total De Novo requests			52		7,280	$6,308
Request for withdrawal	5	1	5	10	50	$5
Total					7,330	$6,313

[1] There are no capital costs associated with this collection of information.

FDA estimates from past experience with the De Novo classification program that the complete process involved with the program under section 513(f)(2)(i) of the FD&C Act takes approximately 100 hours, and the complete process under section 513(f)(2)(ii) of the FD&C Act takes approximately 180 hours. This includes the time for any supplements or amendments to the original submission. We estimate that requests for withdrawal take approximately 10 minutes. The average burdens per response are based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related materials), have consulted and advised manufacturers on the submissions, and have reviewed the documentation submitted.

Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. It is expected that the number of De Novo requests will reach a steady rate of

[1] See the eCopy guidance, "eCopy Program for Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff," at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313794.pdf*.

approximately 52 submissions per year. We expect that we will receive approximately five requests for withdrawal per year.

The operating and maintenance cost for a De Novo submission includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo submission to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy). The annual cost estimate for De Novo submissions is $6,308 (rounded) (52 submissions x $121.30). We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy). The annual cost estimate for requests for withdrawal is $5.

The draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910-0120.

Dated July 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16230 Filed: 8/1/2017 8:45 am; Publication Date: 8/2/2017]